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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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|-----------------|-------------|----------------------|---------------------|------------------|

09/730,525

12/05/2000

Eric R. Ward

PB/5-20757G

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10/21/2002

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EXAMINER

HORLICK, KENNETH R

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/730,525

Applicant(s)

WARD ET AL.

Examiner

Kenneth R Horlick

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1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-13, 15-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 5-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

1. Claim 21 is objected to because of the following informality: "wherein wherein" in line one. Correction is required.

2. Claim 25 is objected to as being identical to claim 23. Correction is required.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-20, 22, 23, and 25 are rejected under 35 U.S.C. 103(a) as being obvious over Ward et al. (US 5,767,373) in view of Zhao et al. (admitted prior art on page 41 of the specification).

The applied reference ('373) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

These claims are drawn to a method of forming a mutagenized DNA encoding a protox enzyme having enhance tolerance to a herbicide comprising subjecting at least two non-identical protox template DNA molecules to a mutagenesis procedure known in the prior art as "staggered extension process" or "StEP".

Ward et al. disclose eukaryotic protox nucleic acid sequences, and mutagenesis thereof for the purpose of creating herbicide-tolerant variants for use in plants (see entire patent, especially column 17, lines 12-44).

Ward et al. do not disclose "StEP" as a means of mutagenizing protox nucleic acids.

Zhao et al. disclose the "StEP" method of mutagenesis/in vitro recombination, whereby at least two enzyme variant nucleic acids are recombined to form a new variant optimized for a desired quality (such as thermostability) (see entire reference, especially Fig. 1 on page 259).

One of ordinary skill in the art would have been motivated to apply the StEP mutagenesis method to the protox nucleic acids of Ward et al. because Zhao taught the advantages of StEP in obtaining recombined nucleic acids with optimal activities. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

4. Claim 21 is rejected under 35 U.S.C. 103(a) as being obvious over Volrath et al. (US 5,939,602) in view of Zhao et al. (admitted prior art on page 41 of the specification).

The applied reference ('602) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR

1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

This claim is drawn to the method as rejected above, wherein at least one of the protox template DNA molecules encodes one of the recited specific amino acid substitutions with respect to the wild-type protox sequence.

Volrath et al. disclose eukaryotic protox nucleic acid sequences, and mutagenesis thereof for the purpose of creating herbicide-tolerant variants for use in plants. Further, this patent discloses the protox mutant-encoding nucleic acids as required in the claim (see columns 11-17).

Ward et al. do not disclose "StEP" as a means of mutagenizing protox nucleic acids.

Zhao et al. disclose the "StEP" method of mutagenesis/in vitro recombination, whereby at least two enzyme variant nucleic acids are recombined to form a new variant optimized for a desired quality (such as thermostability) (see entire reference, especially Fig. 1 on page 259).

One of ordinary skill in the art would have been motivated to apply the StEP mutagenesis method to the protox nucleic acids of Volrath et al. because Zhao taught the advantages of StEP in obtaining recombined nucleic acids with optimal activities. It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-20, 22, 23, and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 5,767,373 in view of Zhou et al. Patented claim 17 is drawn to a plant having altered protox activity which confers tolerance to a herbicide. As noted above, Zhou et al. teaches a means of providing for a mutant nucleic acid encoding an optimized enzyme of interest. One of ordinary skill in the art would have been motivated to carry out the instantly claimed methods because the patented claim clearly provides

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motivation to obtain protox mutants conferring herbicide tolerance, and Zhou et al. provided an advantageous means of creating mutants having desirable properties.

6. Claim 21 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-121 of U.S. Patent No. 5,939,602 in view of Zhou et al. The patented claims are drawn to nucleic acids encoding a large number of modified/substituted protox enzymes with altered activity which confer tolerance to a herbicide. As noted above, Zhou et al. teaches a means of providing for a mutant nucleic acid encoding an optimized enzyme of interest. One of ordinary skill in the art would have been motivated to carry out the instantly claimed method because the patented claims clearly provide motivation to obtain protox mutants conferring optimal herbicide tolerance, and Zhou et al. provided an advantageous means of creating mutants having desirable properties.

7. No claims are free of the prior art.

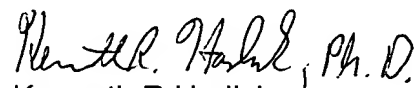
8. The following patents with common inventors are made of record as references of interest: Ward et al. (US 6,288,306, US 6,307,129, US 6,177,245, US 6,282,837) and Volrath et al. (US 6,308,458 and US 6,084,155).

9. Stemmer (US 2002/0059659) and Subramanian et al. (US 2002/0058249), which are not prior art, are made of record as disclosing and claiming an invention similar to that of the instant application.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Kenneth R Horlick
Primary Examiner
Art Unit 1637

October 10, 2002